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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,477	06/23/2006	Thomas Hille	RO4283US (#90568)	3321

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EXAMINER	
BARHAM, BETHANY P	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,477	HILLE ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Applicant's response on 6/9/09 is acknowledged. Claims 1-23 and 25-47 are pending.

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on 6/9/09 is acknowledged. The traversal is on the ground(s) that GB 1161528 fails to teach the process of the presently claimed invention. This is not found persuasive because Groups I-VIII are not only drawn to process claims. Specifically, as pointed out in the 5/13/09 Election/Restriction requirement, Group I is drawn to a wound dressing and GB 1161528 teaches the same wound dressing composition. The fact that the instant group I claims are product-by-process claims does not make them patentable, see MPEP 2113 "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). As such, claims 1-15, 18-32, 35, 38-41 and 44-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Claims 16-17, 33-34, 36-37 and 42-43 will be

examined in the instant application. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/9/09. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not teach "a solvent", there are no solvents disclosed in the instant specification.

Claim 17 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not teach at least one "further vasoconstrictive medicinal substance", other than adrenaline and salts thereof of claim 16 and no other sympathomimetics are taught other than adrenaline/noradrenaline (pg. 3, 2nd paragraph). It is noted that noradrenaline is the

next lower homolog of adrenaline and that the two structures differ only in that adrenaline has a methyl group attached to its nitrogen, while the methyl group is replaced by a hydrogen atom in noradrenaline.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17, 33-34, 36-37 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,236,633 ('633) in view of US 2005/0075597 ('597) and further in view of 20030124176 ('176).

The instant claims are drawn to a process for producing a wound dressing for covering bleeding wounds, said wound dressing being a ready-made product and comprising a carrier material containing a compound selected from the group consisting of adrenaline and one of the pharmaceutically acceptable salts of adrenaline, wherein said compound is a vasoconstrictive medicinal substance, the process comprising at least the steps of: a) degassing a defined amount of a solvent or solvent mixture by using a light-impermeable vessel, or selecting and providing a solvent or solvent mixture which does not adversely affect the stability of a medicinal Substance that is instable in

the presence of oxygen; b) adding a defined amount of a vasoconstrictive medicinal substance selected from the group consisting of adrenaline and one of - the pharmaceutically acceptable salts of adrenaline; c) dissolving the medicinal substance in the solvent or solvent mixture; d) removing a partial amount of the solution and dripping the partial amount of the solution onto a carrier material; e) drying and removing the solvent or solvent mixture; and f) repeating steps d) and e), if required.

- '633 is directed to a process for preventing decomposition by oxidation of substances in pharmaceutically active preparations in the form of solutions and that such compositions are packaged in oxygen impervious material (abstract). According to '633 adrenaline is easily affected by oxygen and decomposes to non-active compounds (col. 1, lines 25-35). The composition of '633 contains an active solution and a compound of adrenaline, noradrenaline and derivatives thereof formed under an inert gas such as nitrogen, argon, etc (col. 2, lines 13-50). According to '633 a solution with adrenaline bitartrate and lidocaine HCl is formed in the presence of nitrogen gas in glass ampoules and packaged in an aluminum foil-plastic foil casing after 1 hour no amounts of free oxygen are present in the package (col. 3, lines 20-42) (meeting the limitations of claim 16a-c and 17). It is noted that lidocaine has direct vasoconstrictive effects in the cited as interest Tototama et al (abstract).
- '633 does not teach the process for producing a wound dressing for covering bleeding wounds or "d) removing a partial amount of the solution and dripping the

partial amount of solution onto a carrier material; e) drying and removing the solvent or solvent mixture and f) repeating steps d) and e) if required."

- '597 teaches a method and kit for reducing vascular access complications by applying a post-hemodialysis compression to stop bleeding (abstract, claim 1 [0004, 0015, 0030]) and according to '597 the compression can comprise a vasoconstrictor such as adrenaline and norepinephrine (aka noradrenaline) ([0032, 0058], claims 28-29) formed with a pharmaceutical carrier like water, salt, sugar solutions, etc [0065] and a film, mat, membrane, microbead, etc with a neutral solid such as a gauze, bandage, or barrier forming material like woven polymer fibers ([0039, 0055], claims 30 and 40-45). The formulation can be made by adding the vasoconstrictor composition (in the form of a liquid, solution, gel, etc) onto the barrier material [0073-0076, 0094]. The kit contains the composition which is dipped/added/applied to the barrier material within a sealed, waterproof, sterile package (such as aluminum foil, plastic, etc) for removal without contamination [0162]. Note the Examiner is interpreting the dipped/adding/application of the composition to the carrier/barrier material of '597 as meeting the limitation of instant claim 16d.
- The barrier materials of '597 are not taught to have any peroxide content and are gauze or woven polymer fibers (according to the instant specification carrier materials include gauze, compresses, papers, synthetic fibers, etc (pg. 4-5) meeting the limitations of claims 36-37 and 42).

- '597 teaches one or more vasoconstrictor agents such as adrenaline and norepinephrine (aka noradrenaline), which are sympathomimetics according to the instant specifications pg. 3 (claims 28-29; [0058,0164]).
- '633 or '597 do not teach "e) drying and removing the solvent or solvent mixture" of instant claim 16, but '597 does teach applying the formulation to a barrier material and formulating a patch [0073-0078, 0094] and using a pre-formed HealTekPatch™.
- '176 teaches that patches are formulated by coating the active onto a release liner and drying them to remove water and other solvents producing a dried drug-in-adhesie/release liner film [0266].
- '633, '597 and '197 do not teach the dripping and drying steps are carried out under protective gas (instant claims 33-34), but '633 teaches the technique of making adrenaline compositions under inert gases (col. 2, lines 13-50; col. 3, lines 20-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '633 in view of '597 and '176. The combination of a known process '633 and a known product '597 and '176 is within the purview of the skilled artisan and would yield predictable results. One of ordinary skill in the art would know how to combine the known '633 process for making a stable adrenaline composition in an inert atmosphere with the known wound care patch of '597 that is dried according to '197 in order to produce an adrenaline patch formed in an inert atmosphere for wound care with predictable results. A skilled artisan would be motivated to modify the patch of

'597 and '197 with reasonable expectation of success since '633 teaches that adrenaline compositions are easily affected by oxygen and decompose to non-active compounds (col. 1, lines 25-35) and that stable adrenaline compositions are formed.

Cited As Interest

Tototama et al (1997) "Lidocaine-induced hemodynamic effects are enhanced by the inhibition of endothelium-derived relaxing factor in dogs" teaches that lidocaine has direct vasoconstrictive effects (abstract).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Supervisory Patent Examiner, TC 1600